

LIDEXA- lidexa cream
Oncora Pharma, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Lidexa

DESCRIPTION

Lidexa™ (Lidocaine Hydrochloride) Cream 38.8

INDICATIONS AND USAGE

Lidexa™ is indicated for topical analgesia as directed by a healthcare provider.

CONTRAINDICATIONS

Lidexa™ is contraindicated in patients with known hypersensitivity to lidocaine or any component of the formulation.

WARNINGS

For external use only. Not for ophthalmic use.

Avoid contact with eyes.

Excessive application may result in increased systemic absorption.

Keep out of reach of children.

PRECAUTIONS

Use only as directed. If irritation occurs, discontinue use and consult a healthcare provider.

General

Drug Interactions

Carcinogenesis, Mutagenesis, Impairment of Fertility

Pregnancy

Nursing Mothers

Pediatric Use

ADVERSE REACTIONS

Localized skin reactions such as redness, irritation, or rash may occur.

DOSAGE AND ADMINISTRATION

For topical use only.

Apply to the affected area 3 to 4 times daily or as directed by a healthcare provider.

HOW SUPPLIED

Lidexa™ (Lidocaine Hydrochloride 38.8 mg/g) is supplied as a white topical cream in a 3 oz (85 g) tube.

NDC 85477-330-07

PRINCIPAL DISPLAY PANEL

For RX only

NDC: 85477-330-07



KEEP OUT OF REACH OF CHILDREN
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Net Wt. 3 oz. (85g)



DIRECTIONS: Apply Lidexa to the skin 3 to 4 times daily or as directed by a healthcare provider.

WARNINGS: Do not use this product if you are allergic to any of the ingredients. Avoid contact with eyes.

STORAGE: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

Active Ingredients: Lidocaine HCl 3.88%

Inactive Ingredients: Aqua (Water), Cyclopentasiloxane, Dimethicone, Capric/Capryl triglyceride, Cetyl Alcohol, Glyceryl Stearate, PEG-75 Stearate, Ceteth-20, Steareth-20, Prunus Amygdalus Dulcis oil, Stearyl alcohol, Phenoxyethanol, Ethylhexylglycerin, Sodium Hydroxide, Lactic Acid.



Manufactured for:
Oncora Pharma
Dallas, TX, 75228

pdp

LIDEXA

lidexa cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85477-330
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	38.8 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-	85 g in 1 BOTTLE, PUMP; Type 0: Not a	02/26/2026	

330-07	Combination Product	02/20/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/26/2026	

Labeler - Oncora Pharma, LLC (119482542)

Revised: 2/2026

Oncora Pharma, LLC